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<u>REMARKS</u>

Claims 38, 41, 60 and 72 have been amended.

Claims 61-63 and 73-75 have been cancelled.

Claim 84 has been added.

35 U.S.C. §112

The claims have been amended to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Claim 38 has been amended to change the limitation "holder" to "holder tube," thereby correcting a typographical error in the claim. Antecedent basis for the amended limitation is provided in the claim.

Claim 41 has been amended to change the limitation "the holder tube and expander" to "the holder tube and the expander" in order to enhance clarity, as suggested by the Office Action.

Applicants believe claims 38 and 41 are now in condition for allowance.

35 U.S.C. §102

MPEP 2131 quotes <u>Verdegaal Brothers v. Union Oil of California</u>, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if <u>each and every element</u> as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 38-59

Claim 38 claims an anastomosis device deployment system comprising a handle, a holder tube attached to the handle, the holder tube having a distal end configured to hold the

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anastomosis device with an attached graft vessel, and an expander positioned within the TER 3700 holder tube and slidable with respect to the holder tube to a position at which the expander is positioned within the anastomosis device and radially expands the anastomosis device.

U.S. Pat. No. 6,193,734 to Bolduc ("Bolduc") neither teaches nor suggests each and every element of claim 38. For example, Bolduc neither teaches nor suggests an anastomosis device, nor does it teach or suggest a holder tube having a distal end configured to hold the anastomosis device with an attached graft vessel. Further, Bolduc does not teach or suggest an expander positioned within the holder tube and slidable with respect to the holder tube to a position at which the expander is positioned within the anastomosis device and radially expands the anastomosis device. In contrast, Bolduc discloses the use of a plurality of independent tissue securing members 14B. (column 7, line 61 through column 8, line 24; Figures 10-12). "The applier supports a plurality of tissue securing members 14B." (column 8, lines 2-3; emphasis added). The "plurality of tissue securing members are collapsed against first and second tissue structures by an applier." (column 7, lines 63-64; emphasis added). Figures 1-2 also illustrated the plurality of tissue securing members supported by the applier. Because a plurality of tissue securing members are utilized to connect the graft vessel to the target vessel, rather than a unitary anastomosis device, Bolduc neither teaches nor suggests an anastomosis device. Bolduc thereby can neither teach nor suggest radial expansion of an anastomosis device, with an expander or any other structure or mechanism.

Thus, Bolduc neither teaches nor suggests each and every element claimed in claim 38, and Applicants consequently believe claim 38 is in condition for allowance. Claims 39-59 depend directly or indirectly from independent claim 38. Thus, dependent claims 39-59 are believed to be in condition for allowance as well.

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Claims 60, 64-71

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Claim 60 claims a tool for deploying an anastomosis device, comprising a first member configured to hold the anastomosis device, a second member, said first member and said second member slidable relative to one another, wherein relative motion of said first member and said second member causes deformation of the anastomosis device, and a handle connected to at least one of said first member and said second member, wherein rotation of said handle about an axis causes said first member and said second member to slide relative to one another.

U.S. Pat. No. 6,152,937 to Peterson ("Peterson") neither teaches nor suggests each and every element of claim 60. The Office Action states that Peterson discloses "a handle, which is the proximal end of first member 58." (Office Action, page 3). However, Peterson neither teaches nor suggests a handle. Further, claim 60 claims a handle that is a separate element from the first member and connected to the first member. Peterson does not disclose or suggest such a handle. Even if the proximal end of the first member 58 were to be considered a handle, which Applicants do not concede, Peterson discloses nothing about the rotation of the first member, much less relative sliding motion between the first member and the second member as a result of that rotation. Peterson merely teaches sliding a first member relative to a second member, and neither teaches nor suggests rotating the first member to cause such sliding. (e.g., column 9, lines 26-29; Figure 12).

Bolduc neither teaches nor suggests each and every element of amended claim 60. Bolduc neither teaches nor suggests "a handle ... wherein rotation of said handle about an axis causes said first member and said second member to slide relative to one another." Bolduc teaches a deployment tool 50 having a plunger 64 that is actuated to deploy a plurality of anastomosis hooks 80. (e.g., column 10, lines 60-66, Figure 16). The end 88 of the plunger 64 is "depressed" to perform this actuation, such that the plunger 64 translates forward

relative to a remainder of the deployment tool 50. Thus, Bolduc merely teaches sliding a first member relative to a second member, and neither teaches nor suggests rotating the first member to cause such sliding.

Thus, neither Peterson nor Bolduc teach nor suggest each and every element claimed in claim 60, and Applicants consequently believe claim 60 is in condition for allowance.

Claims 64-71 depend directly or indirectly from independent claim 60. Thus, dependent claims 64-71 are believed to be in condition for allowance as well.

Claims 72, 76-84

The discussion above with regard to claim 60 applies equally to claim 72. Neither Peterson nor Bolduc teach nor suggest each and every element claimed in claim 72, and Applicants consequently believe claim 72 is in condition for allowance. Claims 76-84 depend directly or indirectly from independent claim 72. Thus, dependent claims 76-84 are believed to be in condition for allowance as well.

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

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Claims 45, 49

Claims 45 and 49 each depend from independent claim 38. As discussed above,

Bolduc does not teach or suggest all of the elements of claim 38. Because claims 45 and 49

depend from claim 38, claims 45 and 49 each include all the elements of claim 38. Thus,

Bolduc meither teaches nor suggests all of the limitations of claims 45 and 49.

Applicants also note that the end 88 of the plunger 64 is identified as corresponding to the handle claimed in claims 38, 45 and 49. (e.g., column 10, lines 60-61). The plunger 64 moves linearly, and Bolduc neither teaches nor suggests rotation of the handle, much less rotation of the handle to cause a first member and a second member to slide relative to one another.

Consequently, a prima facie case of obviousness has not been established, and Applicants believe that claims 45 and 49 are in condition for allowance.

REQUEST FOR ALLOWANCE

Entry of this amendment and allowance of pending claims 38-60, 64-72 and 76-84 are respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,

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Version with Markings to Show Changes Made

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- 38. (Amended) An anastomosis device deployment system comprising:
 - a handle;
 - a holder tube attached to the handle, the holder tube having a distal end configured to hold the anastomosis device with an attached graft vessel; and an expander positioned within the holder tube and slidable with respect to the holder to a position at which the expander is positioned within the anastomosis device and radially expands the anastomosis device.
- 41. (Amended) The system of claim 38, wherein the handle includes two cam grooves, and the holder tube and the expander each have a follower member engaged in one of the cam grooves to move the holder tube and the expander with respect to one another upon activation of a trigger of the handle.
- 60. (Amended) A tool for deploying an anastomosis device, comprising:
 - a first member configured to hold the anastomosis device; [and]
 - a second member, said first member and said second member slidable relative to one another, wherein relative motion of said first member and said second member causes [radial expansion] <u>deformation</u> of the anastomosis device; and
 - wherein rotation of said handle about an axis causes said first member and said second member, wherein rotation of said handle about an axis causes said first member and said second member to slide relative to one another.

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72. (Amended) An anastomosis system, comprising:

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- an anastomosis device deployable from a first configuration to a second configuration, wherein said second configuration includes at least one flange;
- a first member configured to hold [the] said anastomosis device; [and]
- a second member; said first member and said second member slidable relative to one another, wherein motion of at least part of said first members deploys at least one said flange of said anastomosis device; and
- a handle connected to at least one of said first member and said second member,

 wherein rotation of said handle about an axis causes said first member and said

 second member to slide relative to one another.